

2003

WHAT IS CLAIMED IS:

Sub. a!

~~1. A stable pharmaceutical composition in the form of a nonirritating emulsion comprising at least one cyclosporin in admixture with a higher fatty acid glyceride and polysorbate 80.~~

2. The pharmaceutical composition according to claim 1 wherein the cyclosporin comprises cyclosporin A.

a
a

3. The pharmaceutical composition according to claim 2 wherein ~~a~~^{the} weight ratio of the higher fatty acid glyceride to the polysorbate 80 is between about 0.3 ~~to~~^{and} about 30.

Sub. a2

~~4. The pharmaceutical composition according to claim 3 wherein a weight ratio of cyclosporin to castor oil is below about 0.16.~~

5. A pharmaceutical composition in the form of a nonirritating emulsion comprising at least one cyclosporin in admixture with castor oil and polysorbate 80.

~~6. The pharmaceutical composition according to claim 5 wherein the cyclosporin comprises cyclosporin A.~~

a
a

7. The pharmaceutical composition according to claim 6 wherein ~~a~~^{the} weight ratio of castor oil to the polysorbate 80 is between about 0.3 ~~to~~^{and} about 30.

~~8. The pharmaceutical composition according to claim 7 wherein the weight ratio of castor oil to cyclosporin is below about 0.16.~~

Sub. a3
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8. The composition according to claim 1 wherein the higher fatty acid glyceride and polysorbate 80 are present in amounts sufficient to prevent crystallization of cyclosporin for a period of up to about nine months.

10. A stable, nonirritating ophthalmic composition comprising cyclosporin in admixture with an emulsifying amount of a higher fatty acid glyceride and polysorbate 80.

11. The composition according to claim 10 wherein the cyclosporin comprises cyclosporin A.

12. The composition according to claim 11 wherein the higher fatty acid glyceride comprises castor oil.

13. The composition according to claim 12 wherein a weight ratio of castor oil to the polysorbate 80 is between 0.3 to about 30.

14. The composition according to claim 13 wherein the weight ratio of castor oil to cyclosporin is below 0.16.

15. The composition according to claim 14 wherein the weight ratio of castor oil to polysorbate 80 is between 0.5 and 12.5, and the weight ratio of castor oil to cyclosporin is between about 0.12 and about 0.02.

16. A pharmaceutical composition in the form of a nonirritating emulsion comprising an active agent having poor water solubility in admixture with a higher fatty acid glyceride and polysorbate 80.

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17. The composition according to claim 10 wherein the emulsifying amount of higher fatty acid glyceride and polysorbate 80 is sufficient to prevent crystallization of cyclosporin for a period of up to about nine months.

18. The composition according to claim 16 wherein the active agent comprises a steroid.

19. The composition according to claim 16 wherein the active agent comprises indomethacin.

20. The composition according to claim 18 where the steroid is selected from a group consisting essentially of androgen, prednisolone, prednisolone acetate, fluorometholone, and dexamethasone.

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21. The composition according to claim 16 wherein the emulsifying amount of higher fatty acid glyceride and polysorbate 80 is sufficient to prevent crystallization of cyclosporin for a period of up to about nine months.

add a⁴